Juanita R. Brooks (CA Bar No. 75934) (brooks@fr.com)
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070 / Fax: (858) 678-5099

Craig E. Countryman (CA Bar No. 244601) (countryman@fr.com)
FISH & RICHARDSON P.C.
555 W. 5th Street, 31st Floor
Los Angeles, CA 90013
Telephone: (213) 533-4240 / Fax: (213) 996-8304

Jonathan E. Singer (CA Bar No. 187908) (singer@fr.com)
Michael J. Kane (*pro hac vice*) (kane@fr.com)
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070 / Fax: (612) 288-9696

Susan M. Coletti (*pro hac vice*) (coletti@fr.com)
Elizabeth M. Flanagan (*pro hac vice*) (eflanagan@fr.com)
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19899
Telephone: (302) 652-5070 / Fax: (302) 652-0607

Attorneys for Plaintiffs
ALLERGAN USA, INC. and
ALLERGAN INDUSTRIE, SAS

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

PLAINTIFFS' RESPONSIVE CLAIM CONSTRUCTION BRIEF

Date: July 22, 2014
Time: 9:00 am
Ctrm: 10D
Judge: Hon. Andrew J. Guilford

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I. INTRODUCTION

Defendants' proposed constructions hinge on claim construction principles that apply only with the support of clear, unmistakable, and unambiguous evidence—lexicography ("stable"); disclaimer premised on use of the phrase "present composition" (the "crosslinked HA" terms); and prosecution history disclaimer ("uncrosslinked HA"; "free HA"). No such evidence exists here. Instead, the record supports Allergan's proposed constructions, which capture the disputed terms' plain meanings as informed by the intrinsic record and which the Court should adopt over Defendants' litigation-driven constructions.

II. ARGUMENT

A. '475 Patent: Stable

Since submitting opening briefs, Defendants cut back their proposed construction of "stable" by removing the reference to a "sterile composition" that has been "stored at about 25C for about two months." Defendants apparently realized—correctly—that these proposed limitations were indefensible. Moreover, both of those concepts conflicted with their lexicography argument because they appear nowhere in the definition Defendants rely upon. However, removing these unsupported limitations does not salvage Defendants' current construction.

Even the Defendants' newly proposed construction for "stable" is ***not*** a "direct quote of the definition given by the patentee in the specification," as they claim. (D.I. 53 at 7.) Rather, it borrows portions of the definition of different terms that do not appear in the claims—"***autoclave stable*** or ***stable to autoclaving***." (*See* '475 patent at 4:41-48.) Indeed, Defendants' construction omits from that definition the language "product or composition that is resistant to degradation" and "effective autoclave sterilization." (*Id.*)

Defining a narrow, qualified term such as "autoclave stable" in the specification does not limit the full scope of a broader, unqualified term such as

"stable" that appears in the claims. *See Kumar v. Ovoniv Battery Co., Inc.*, 351 F.3d 1364, 1369 (Fed. Cir. 2003) (finding no lexicography where the specification did not indicate that "'completely amorphous' was used synonymously with the [broader] term 'amorphous'" that appeared in the claims). Here, the claims use the broad term "stable," not "autoclave stable," so the patent's description of "autoclave stable" should not limit the scope of the claims. This is especially so because the term "autoclave stable" relates to only one of several embodiments and conflicts with the specification's broad discussion of stability. (*See, e.g.*, '475 at 2:7-24 (describing stability in vivo); *see also* D.I. 58 at 8-9.) *See Optimal Recreation Solns. LLP v. Leading Edge Techs., Inc.*, 6 F. App'x 873, 876–77 (Fed. Cir. 2001) (finding no lexicography or limitation of the broad term "position" through specific examples in the specification such as "actual position" or "corrected position").

Defendants' case law does not support their erroneous lexicography theory. In *SunRace Roots Enterprise Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 1308 (Fed. Cir. 2003), the court considered claim differentiation and lexicography arguments before ***reversing*** an "unduly restrictive" claim construction "because the intrinsic evidence [did] not clearly narrow the [disputed] term." In *3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003), the court construed the disputed claim term "embossed" according to the "expressly" provided definition in the specification: "'[e]mbossed' means . . . ." *3M* is unlike the present situation where the '475 patent defines the term "autoclave stable" but the claims use the term "stable." *3M* does not suggest that a court may apply the specification's definition of a non-claim term to a different claim term. *See id.*

B. The '475 and '795 Patents: The "Crosslinked HA" Terms

None of the three ways in which Defendants' constructions for the "crosslinked HA" terms depart from Allergan's constructions is supported by the record or the law. The Court should reject Defendants' constructions.

1. "chemical linking" versus "covalently modified"

Defendants' inclusion of the phrase "covalently modified" in their constructions of the "crosslinked HA" terms is unnecessary and wrongly describes crosslinking. Introducing a confusing technical concept into the claims by specifying a kind of chemical link made between the HA polymers to form crosslinked HA will not aid the jury. *See Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 528 F. Supp. 2d 967, 982 (N.D. Cal. 2007) (explaining that "the purpose of claim construction is to resolve disputed meanings and technical scope in order to aid the fact-finder," including lay jurors). Further, Defendants inject ambiguity into the claims with the term "modified." As explained in Allergan's opening brief, the term "modified" is ambiguous because it may suggest that crosslinked HA includes HA polymers that have reacted with only one end of a crosslinking agent and thus do not form the "intermolecular junctions" associated with the macromolecular structure of crosslinked HA. (D.I. 58 at 14; *see also* '475 patent at 4:62-65; '795 patent at 5:43-46.) In other words, not all "covalently modified" HA polymers are crosslinked. Allergan's constructions, which refer to "chemical linking of HA" by BDDE or a crosslinking agent, more simply and accurately describe crosslinked HA in view of the specification.

2. "water-insoluble"

There is no basis to construe the "crosslinked HA" terms in part as "water-insoluble." Unable to find the word "water-insoluble" in the patents, Defendants attempt to support their "water insoluble" limitation by pointing to the specifications' description of crosslinked HA as "particles in a substantially solid phase" and summarily concluding that "water insoluble" and "solid phase" are synonymous. (D.I. 53 at 10.) However, that argument fails to take into account other embodiments of the invention which include "swollen gels [that] are highly cohesive with no visible distinct particles." ('475 patent at 9:61-63; '795 patent at

10:52-54.) Thus, the specifications teach that the claimed crosslinked HA may or may not exist as particles. Accordingly, the specifications' reference to embodiments including a "solid phase" of particles is no basis for adding "water insoluble" to the claims.

Having failed to find support in the patents being construed, Defendants vainly cite various other patent references to suggest that the art recognizes that the claimed crosslinked HA is water-insoluble. But none of these references actually discusses the disputed claim terms. Rather, those references concern different HA compositions crosslinked with various different crosslinkers. (*See* D.I. 54-4 (Sadozai)) at 2:6-15 (urea crosslinker); D.I. 54-2 (Calias) at 3:15-26 (DVS crosslinker); D.I. 54-5 (Debacker) at 9:20-33 (DVS, BDDE and other crosslinkers); D.I. 54-6 (Lebreton) at [0011] (unspecified crosslinker).) As such, these references say nothing about the disputed claim terms or how they should be construed. *See Chip-Mender, Inc. v. Sherwin-Williams Co.*, 458 F. Supp. 2d 994, 1002–04 (N.D. Cal. 2006) (construing the disputed claim term consistent with its use in the specification rather than its use in external references where the references were not discussed in prosecution or expressly adopted by patentee as controlling).

3. "degree of crosslinking"

The specifications do not disclaim crosslinked HA compositions that fall outside the "about 2% to up to about 20%" degree-of-crosslinking range. The "present invention" line of cases Defendants rely on for their disclaimer argument is not applicable here, where Defendants rely on one single description of the "present compositions" that is not used uniformly throughout the specification. Because the patentee did not uniformly refer to the inventive HA compositions as being limited to a degree of crosslinking between about 2% and up to about 20%, Defendants' argument based on "present invention" case law fails. *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136 (Fed. Cir. 2011) ("[U]se of the phrase

'present invention' or 'this invention' is not always so limiting, such as where the references to a certain limitation as being the 'invention' are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent."); *see Voda v. Cordis Corp.*, 536 F.3d 1311, 1320–22 (Fed. Cir. 2008).

Here the patents state: "The present invention generally relates to injectable soft tissue fillers and more specifically relates to hyaluronic acid-based dermal and subdermal fillers including an anesthetic agent." ('475 patent at 1:16-19; '795 patent at 1:16-19.) This broad description of the "present invention"—without reference to limits on degree of crosslinking—is significant evidence that there is no disclaimer of compounds with a degree of crosslinking outside the 2-20% range. *Fastenetix, LLC v. Medtronic Sofamor Danek, Inc.*, No. 06-2070, 2007 WL 2159613, at *15–16 (D.N.J. July 25, 2007) (refusing to limit claims to a narrow description of "present invention" in light of broad statements of the "invention").

Further contradicting Defendants' disclaimer argument, the patents repeatedly teach that the claimed compositions are not restricted to a degree-of-crosslinking lower bound of 2% and upper bound of 20%. Indeed, the patents include some embodiments where the degree of crosslinking is "less than about" some percentage with no express lower bound. (*See, e.g.*, '475 patent at 3:22-26 ("less than about 5%, for example, about 2%"), 3:63-64 ("less than about 6% or less than about 5%"), 4:17-18 ("less than about 5%"); 9:35-37 ("less than about 6%, for example, less than about 5%.").) Defendants are reading into these examples that the degree of crosslinking is "less than about" the recited percentage ***and greater than about 2%***, based on one disclosed embodiment with a degree of crosslinking between about 2% and 20%. But that is not how the specifications or plain language of the claims describe all embodiments, and the claims should not be so limited.

The patents also use the phrase "present composition" in several other places without reference to degree of crosslinking, indicating that a specific degree of

crosslinking is not a feature of the inventions. (*See* '475 patent at abstract, 2:42-48, 5:31-38 (referring to stability features); *id.* at 4:52-54, 8:23-30 (referring to HA molecular weight); *id.* at 7:20-23 ("in some embodiments," the present compositions are particulate), *id.* at 7:65-8:12 (referring to sterility and stability features).)

The structure of the patents' claims further confirms that a 2-20% degree of crosslinking limitation was not intended to be a feature of the invention as a whole. Whereas independent claim 1 of the '475 patent is silent as to the degree of crosslinking, independent claim 27 covers the exact embodiment Defendants' suggest should limit all the claims. (*Compare* '475 patent at 9:31-33, *with* claim 27.) And ***none*** of the claims of the '795 patent refer to any specific degree of crosslinking. ('795 patent at 19:20-22:27.)

None of Defendants' cases compel a finding of disclaimer because their facts are readily distinguishable. *Honeywell, Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318–19 (Fed. Cir. 2006) (limiting "fuel injection system" to "fuel filter" based on four references to a fuel filter as the "invention" and no indication a fuel filter was just a preferred embodiment); *Astrazeneca AB v. Hanmi USA, Inc.*, 554 F. App'x 912, 915–16 (Fed. Cir. 2013) (limiting claimed "alkaline salts" to the six cations disclosed in the specification where the "invention" was only described with reference to those six cations).

Defendants also now contend for the first time that the "crosslinked HA" terms are invalid as indefinite if they do not incorporate Defendants' 2-20% degree-of-crosslinking limitation. As an initial matter, Defendants' new indefiniteness argument disregards this Court's Order prohibiting Defendants from arguing indefiniteness in the claim construction proceedings on another term where they failed to timely disclose it under the Court's rules.[1] (D.I. 47 at 2.) But, even putting

[1] Like the "by volume" terms underlying the Court's Order, Defendants never contended during the claim construction phase that the "uncrosslinked HA" terms were indefinite and always included the 2-20% degree of crosslinking limitation in their proposed constructions.

this aside, Defendants' indefiniteness argument fails because it is premised on technical arguments about the necessity of a lower bound of 2% degree of crosslinking to distinguish crosslinked HA from lightly crosslinked HA that are based wholly on attorney argument without any expert testimony support. (*See* D.I. 53 at 13.) *Carace v. Meyer Mktg. Co.*, 812 F. Supp. 2d 547, 559–60 (S.D.N.Y. 2011) (rejecting indefiniteness argument premised on mere attorney argument). It is also demonstrably false given the make-up of Defendants' own products, which are publicly described as having crosslinked HA particles with a degree of crosslinking around 1%. (Flanagan Decl., Ex. G (Kablik) at 11, tbl.1.) Thus, as Defendants well know, it is possible to have crosslinked HA with less than a 2% degree of crosslinking.

C. The '475 Patent: "uncrosslinked HA" and "free HA"

The asserted claims of the '475 patent cover compositions that include specific ranges of free HA or uncrosslinked HA. Nothing in the claims requires that the free HA or uncrosslinked HA exist as a by-product of the crosslinking process or be added after the crosslinking process—the claims cover the final composition regardless of the source of the free HA or uncrosslinked HA.

Nonetheless, Defendants rely on the often-argued, rarely-invoked doctrine of prosecution history disclaimer in an attempt to add yet another limitation admittedly not present in the literal language of the claims. Based on their tortured interpretation of the prosecution history, Defendants assert that the claimed "uncrosslinked" and "free" HA must be "added to the crosslinked HA portion of the composition," as opposed to also possibly existing as a by-product of the manufacturing process. But prosecution disclaimer does not attach unless the alleged disavowing statements are clear and unmistakable. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003); *N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1293–95 (Fed. Cir. 2000) (declining to find

disclaimer where the patentees did not act "with reasonable clarity and deliberateness"). Defendants have not identified anything in the prosecution history of the '475 patent that is a clear, unmistakable disclaimer. Nowhere in the prosecution history is there a statement that the invention is limited to compositions where the free HA or uncrosslinked HA is added after the crosslinking process, and Defendants have not identified any such statement. Indeed, as demonstrated by their use of phrases like "in other words" and "following the same logic," Defendants are forced to recharacterize what was conveyed during prosecution to construct their disclaimer arguments about the source of water soluble HA. (D.I. 53 at 16-17.) Clear disavowals do not require such elaboration.

Defendants' argument that the applicant disclaimed compositions in which the claimed uncrosslinked HA is not added until after the crosslinking process relies on correspondence concerning the Lebreton reference. In rejecting claims reciting at least 20% uncrosslinked HA, the examiner stated that Lebreton disclosed a HA composition with a 6.5% degree of crosslinking, and thus disclosed 93.5% uncrosslinked HA. (AGNHA 589-91.) In response, the applicant argued that Lebreton did not disclose any uncrosslinked HA, let alone the claimed amount of uncrosslinked HA. (AGNHA 693-694.) Specifically, applicant stated that based on the 6.5% degree of crosslinking and "absent evidence to the contrary, there is no reason to believe that Lebreton's compositions would have uncrosslinked HA." (*Id.*) The applicant said nothing about the source of the uncrosslinked HA in the claimed inventions, and instead put the burden on the Examiner to show that Lebreton disclosed the claimed amount of uncrosslinked HA, whatever its source. The applicant did not clearly state that, in view of Lebreton, he was limiting the invention to compositions in which the claimed uncrosslinked HA is limited to that which is added after the crosslinking process. Such a limitation would have been inconsistent with the specification's explicit statement that an "amount of residual

free HA [may exist] following crosslinking." ('475 patent at 5:14-21.) The Examiner thereafter withdrew the rejection over Lebreton in light of claim amendments—which also did ***not*** concern the source of the claimed uncrosslinked HA—and the applicant's arguments, without further explanation. (AGNHA 712.)

In an attempt to manufacture a disclaimer where none exists, Defendants extrapolate—without any supporting expert testimony—that if Lebreton's 6.5% degree of crosslinking composition might not include any uncrosslinked HA, then a composition with a 2% degree of crosslinking (a lower limit Defendants read into the asserted claims through the "uncrosslinked HA" terms) likewise would not include any uncrosslinked HA. But Defendants' attorney-argument extension of "logic" is not a "clear and unmistakable" disclaimer of claim scope. The only thing the public would glean from the file history is that, absent any evidence to the contrary, there was no reason to believe the Lebreton reference contained the claimed range of uncrosslinked HA. Nowhere did the applicant clearly and unmistakably limit the source of the claimed uncrosslinked HA to that which is added after crosslinking to overcome the rejection based on the Lebreton reference.

Because applicant did not disclaim free HA or uncrosslinked HA present as a by-product of the manufacturing process, the correspondence concerning the combination of Reinmuller with Lebreton does not "confirm" the alleged disclaimer. After the exchange summarized above, the Examiner acknowledged that Lebreton "lack[ed] a teaching wherein the composition comprises at least about 20% free (uncross-linked) hyaluronic acid." (AGNHA 714.) The Examiner resorted to Reinmuller for the uncrosslinked HA teaching absent from Lebreton. Reinmuller taught "admixing uncross-linked hyaluronic acid to the preparations of exclusively cross-linked hyaluronic acid," and preferably admixing 20% free HA. (AGNHA714-15.) In response, the applicant unsuccessfully argued that "Reinmuller fails to disclose any particular amount of the non-crosslinked HA in

these preparations," and thus "do[es] not disclose, teach or suggest the claimed limitation of 'uncrosslinked HA in an amount of at least 10% by volume.'" (AGNHA 3126-27; AGNHA 3151-52.) Thus, the applicant attempted to distinguish Reinmuller on the grounds that it did not disclose the proper ***amount*** of the claimed uncrosslinked HA; the source of that uncrosslinked HA was not argued by the applicant. (*Id.*) The applicant continued that "***the references, being silent as to an amount of uncrosslinked HA present***, do not even suggest compositions having greater than 10% crosslinked HA." (AGNHA 3127 (emphasis added).) The applicant only argued about the amount of uncrosslinked HA in Reinmuller.

As demonstrated above, the issue during prosecution was whether or not the prior art taught HA compositions with "greater than about 10% uncrosslinked HA" or "at least about 20% free (uncrosslinked) HA" not the source of the uncrosslinked HA. The Applicant never limited—much less clearly and unmistakably limited—the source of the claimed uncrosslinked and free HA to that which is added to the claimed compositions after the crosslinking process. Defendants' construction, which would convert these claims into product-by-process claims, based on prosecution disclaimer should be rejected. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002) (prosecution disclaimer attaches only if "the applicant characterized the invention using words or expressions of manifest exclusion or restriction"); *Vanguard Prods. Corp. v. Parker Hannifan Corp.*, 234 F.3d 1370, 1372–73 (Fed. Cir. 2000) (finding that prosecution history did not support argument that inventors "'expressly disclaimed' claim scope beyond products made by co-extrusion" where prosecution showed applicant and examiner "treated the product claims as directed to the product itself").

III. CONCLUSION

For reasons stated in Allergan's briefing and at argument, Allergan respectfully requests that the Court adopt its proposed constructions.

Dated: June 27, 2014

FISH & RICHARDSON P.C.

By: */s/ Elizabeth M. Flanagan*
Elizabeth M. Flanagan
Attorneys for Plaintiffs
ALLERGAN USA, INC. and
ALLERGAN INDUSTRIE, SAS

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on June 27, 2014 to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Civ. L.R. 5-3.2.2. Any other counsel of record will be served by electronic mail.

/s/ Elizabeth M. Flanagan